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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/574,697 | 04/05/2006 | Jiro Kishimoto | 23757-009US1 / SSD-P848-U | 3729 |
| 26161 | 7590 | 05/07/2009 | EXAMINER | |
| FISH & RICHARDSON PC P.O. BOX 1022 MINNEAPOLIS, MN 55440-1022 | | | KOSAR, AARON J | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 1651 | |
| | | | NOTIFICATION DATE | DELIVERY MODE |
| | | | 05/07/2009 | ELECTRONIC |

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

PATDOCTC@fr.com

Office Action Summary

Application No.

10/574,697

Applicant(s)

KISHIMOTO ET AL.

Examiner

AARON J. KOSAR

Art Unit

1651

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period **will** apply and **will** expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply **will**, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 April 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-39 is/are pending in the application.
- 4a) Of the above claim(s) 1-10 and 17-36 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 11-16 and 37-39 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date: _____.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____.

DETAILED ACTION

Response to Amendment

Applicant's request for reconsideration and amendments filed April 20, 2009, in response to the final rejection are both acknowledged. Upon further consideration, the finality of the last office action is withdrawn in favor of the instant Office Action. Accordingly this action is NON-FINAL.

The claims submitted April 20, 2009 have been entered and are the object of the instant Action. Applicant has amended claim 12 and added new claims 37-39. Claims 1-39 are pending of which claims 1-10 and 17-36 are withdrawn claims. Claims 11-16 and 37-39 are pending and have been examined on the merits. Any rejection and/or objection not specifically addressed is herein withdrawn.

Claim Rejections - 35 USC § 112, 2nd ¶

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 38 is rejected under 35 U.S.C. 112, second paragraph, as failing to set forth the subject matter which applicant(s) regard as their invention. Claim 38 recites the phrase "different mammals, each originating in mice..."; however, it is unclear what the term "each" describes. If Applicant intends for each of the cells to be obtained from a different mammal, wherein each mammal is selected from the group consisting of a mouse, a rat, and ~~or~~ a human, or if some other embodiment is intended, then the claim should so recite. Clarification is required.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 11-16 and 37-39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Inamatsu, *et al* (1998, US 5,851,831 A, of record) in view of Barrandon *et al* (1989, US 4888291 A, reference A).

Inamatsu teaches a composition comprising dermal papilla cells cocultured with mammalian epidermal cells (Example, (2); column 4, "Results", 1st ¶). Inamatsu also teaches varying the animal from which the cells may be obtained, by teaching that epidermal cells may be obtained from "various kinds of epidermal cells of mammals, including rodents and *Hominidae*" (column 2, line 61-64).

Inamatsu does not exemplify a ratio of papilla cells-to-epidermal cells in the composition and does not exemplify compositions comprising cells originating from the mammalian species recited in claims 37-39.

Barrandon teaches that foreskin is a source of epidermal cells by teaching that human epidermal cells may be obtained from foreskin (column 3, ¶ 4).

It would have been obvious to have provided a human, rat, or mouse cell, from the same or different organism, and including the species of human foreskin, because Inamatsu teaches that the epidermal cells are obtained from a skin sample and that epidermal cells may be obtained from a variety of mammalian epidermal cells, including the cells of rodents and *Hominidae*, and because Barrandon teaches that human foreskin is a known source for obtaining epidermis. One would have been motivated to have provided dermal papilla and epidermis from a variety of mammalian sources because Inamatsu is concerned with biotransplantation of hair materials and one would want to provide the composition to a human.

Inamatsu observed a relationship between the proliferation rate of dermal papilla cells and the presence of epidermal cells in culture (column 4, lines 26-31), which is a good place to start in formulating a reason to pick the claimed ratios. I don't want to write it for you, though.

It would have been obvious to have provided a composition having a ratio of dermal papilla cells to epidermal cells including a papilla:epidermal cell ratio of 1:10-10:1 or 1:3-10:1, because Inamatsu teaches a relationship between epidermal cells and the proliferation of ~~an isolated~~ dermal papilla cells (for example column 4, lines 24-31), and one would want to optimize the numbers of the cells in order to optimize this relationship. Accordingly, one would have added any amount of epidermal cells to papilla cells with the expectation that a positive proliferation effect would result and wherein success merely requires contacting/combining the cell species in the composition, which is well within the purview of the skilled artisan.

The composition of Inamatsu, though produced by a different process, appears to be identical to the product by the process of the instant claims 11-16, since Inamatsu teaches a composition comprising features (i.e. mammalian hair dermal papilla cells and epidermal cells) which appear to be substantially

identical to the end product in the instant product-by-process claims. (MPEP 2113). Accordingly the product by process limitations of claims 11 and 13-16 do not appear to affect the patentability of the claims. Burden is shifted to the applicant to show a non-obvious difference.

Accordingly, the invention would have been obvious to one of skill at the time of the invention.

Conclusion

The grounds of rejection have been presented to address the amendments to the claims and new claims 37-39; however, since new grounds of rejection have been presented to address the claimed invention, the instant Action is NON-FINAL.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to AARON J. KOSAR whose telephone number is (571)270-3054. The examiner can normally be reached on Monday-Thursday, 7:30AM-5:00PM, ALT. Friday,EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Wityshyn can be reached on (571) 272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Aaron Kosar/
Examiner, Art Unit 1651

/Lora E Barnhart/
Primary Examiner, Art Unit 1651